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10/044,158	01/11/2002	Claude Jarakae Jensen	10209.388	1070
	7590 06/20/2003			
KIRTON & McCONKIE 1800 Eagle Gate Tower 60 East South Temple Street			EXAMINĘR	
			PATTEN, PATRICIA A	
Salt Lake City, UT 84111			ART UNIT	PAPER NUMBER
		•	1654	
		DATE MAILED: 06/20/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

Application N 10/044,158						
## Examin r Patricia A Patten 1651 The MAILING DATE of this communication appears on the cover sheet with the c resp ndence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed and the period for reply specified adminishing deptine the manifold period of the period for reply specified above. Between the manifold period of the period for reply specified above. Between the manifold period for reply specified above. Between the manifold period for reply specified above. Between the manifold period for reply specified above. Between the manifold period for reply preceived by the Office later than three months after the malling date of this communication. - Failure to reply within the set of extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the malling date of this communication, even if timely filed, may reduce any samed patent term adjustment. See 37 CFR 1.704(b). **Status** 1) Responsive to communication(s) filed on 27 May 2003. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. **Disposition of Claims** 4) Claim(s) 1-16 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) 1-16 is/are rejected. 7) Claim(s) are subject to restriction and/or election requirement. **Application Papers**						
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Application Papers 9)⊠ The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>01 January 2002</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 	al Stage					
14) ☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)						

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 9-16 in Paper No.

10 is acknowledged. Claims 1-8 have subsequently been withdrawn from further

consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected

invention.

Claims 9-16 were examined on the merits.

Specification

The disclosure is objected to because of the following informalities: The recitation of 'morinda citrifolia' is found throughout the specification. It is standard in the art of botany to capitalize the first letter of the Genus; i.e., 'Morinda citrifolia'.

Appropriate correction is required.

Claim Objections

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• Claims 9-16 are objected to because of the following informalities: Claims 9-16 either recite, or depend upon a claim which recites 'morinda citrifolia'. It is standard in the art of botany to capitalize the first letter of the Genus; i.e, 'Morinda citrifolia'.

Claim 13 recites '..are have different concentrations'. This is a minor grammatical error. It appears that the 'are' should be deleted in order to overcome this objection (However, please also see rejection under 35 USC 112 Second paragraph regarding this claim).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 states 'most dilute components'. This phrase is deemed indefinite because the metes and bounds of 'most dilute components' are not clearly delineated. What other components besides water are the Applicant referring to? Because the

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ordinary artisan could not ascertain what is, or is not included in 'most dilute components', the phrase is deemed indefinite. It is suggested that Applicants replace 'most dilute components' with a definite component such as water. It is noted that this claim was examined on the merits as if it were drawn to 'freezing the water of a morinda citrifolia slurry..'.

Claim 9 further recites 'more concentrated portions'. Here, the metes and bounds of 'more concentrated portions' is unknown. First, it is not clear if Applicants intend for this to mean 'more concentrated' than the 'most dilute components'.

Secondly, what portions make up the 'more concentrated portions'? Because the ordinary artisan would not be able to ascertain the 'most dilute components' they could not distinguish what the 'more concentrated' portion is. It is noted that this phrase is recited twice in the claim; lines 4 and 6. It is suggested that Applicants replace 'more concentrated portions' with a definite portion; i.e., components which are not water.

Claim 9 recites 'at a lower temperature'. This phrase is indefinite because 'lower' is an arbitrary term, and the ordinary artisan would not be apprised to a clear temperature value. It appears that Applicants mean that the 'more concentrated portions' are frozen at a lower temperature than the 'most dilute components', however, this is not clear from the wording of the claim.

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While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "extracting" (second instance) in claim 9 is used by the claim to mean "removing or recovering," while the accepted meaning is "to separate from." After the 'most dilute components' are extracted from the 'more concentrated portion', the 'more concentrated portion' is the only matter remaining. Thus, it appears that it is a recovery of the 'more concentrated portions' in contrast to an extraction.

Claim 10 recites 'substantial'. This term is indefinite in that it is a term of degree which has not been clearly defined within the Instant specification. This term will have varying definitions with regard to respective ordinary artisans. It is suggested that Applicants replace this term with a more definite amount to resolve the clarity of the claim. For purposes of searching the prior art, this claim was interpreted to mean that the *Morinda citrifolia* contains pulp.

Claim 11 recites 'said chilling'. This phrase lacks antecedent basis in the claim. It is suggested that Applicants change 'chilling' to 'freezing' in order to overcome this rejection. Claim 11 further recites '..occurs in gradient's associated with the freezing points of said slurry's constituent components'. It is unclear what Applicant means by 'constituent components'. Is Applicant referring to the water portion and the portion that does not contain water? It is known that a juice will contain many inherent

phytochemicals, proteins and polysaccharides just to name a few 'constituents' found in fruit juice. Is Applicant referring to constituents such as polysaccharides and proteins? Thus, the claim lacks clarity as well as clear antecedent basis for the term 'constituent components' because a clear definition of this term was not found in the previous claim nor the Instant specification. This claim was examined on the merits as if it read 'The method of claim 9 wherein the slurry is frozen at an initial temperature to freeze the water in said slurry, and frozen at a second temperature to freeze the non-aqueous portion of said slurry wherein said initial temperature is higher than said second temperature'.

Claim 12 recites 'wherein said constituent's components are removed'. The term 'said constituent's component's' lacks clear antecedent basis in the previous claim because the term 'constituent's' was not mentioned in the previous claim. The Examiner cannot determine what this claim means. Therefore, this claim has not been further treated on the merits.

Claim 13 also recites 'said removed constituent components' which lacks antecedent basis. Also, again, it cannot be determined what the 'components' are that Applicant is referring to. Because this claim is dependent upon an unexamined claim, the Examiner has not treated this claim on the merits.

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Claim 14 recites 'wherein therapeutic oils incorporated in the morinda'. This phrase is confusing in that it can have two meanings. First, it can mean the indigenous therapeutic oils of *M.citrifolia*, or it can mean that therapeutic oils are added to the *M.citrifolia*. It appears, judging from the Instant specification, that Applicants intend for this to mean that the oils which are indigenous to *M.citrifolia* are not volatilized during the process. In either case, Applicants are asked to more clearly state the metes and bounds of this phrase in the claim.

Claim 14 recites 'the process'. This phrase lacks clear antecedent basis because claim 9 recites two method steps. Further, claim 9 recited 'the method'.

Therefore, it is not clear if Applicants mean that the oils are not volatilized during a part of the method, or the entire method.

Claim 15 recites 'retains all of the health benefits of the slurry'. This claim is confusing in that it is not known what 'health benefits' is referring to. Is Applicant using the term 'health benefits' to mean certain phytochemicals? The ordinary artisan would have trouble ascertaining what 'health benefits' the claim is referring to, and thus, the claim is indefinite.

Claims 15 and 16 recite 'wherein the resulting concentrate...'. This phrase lacks clear antecedent basis in the claim, in that the term 'concentrate' was not mentioned previously. In order to overcome this rejection, it is suggested that the term

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'concentrate' appear in claim 9; for example, the last line of the claim may recite 'to form

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a concentrate'.

Claim 17 recites 'therapeutic constituents'. The instant specification does not

define this term. What do Applicants intend for 'therapeutic constituents' to mean?

Because this term is not defined in the Instant specification, the ordinary artisan could

not determine exactly what constituents Applicants consider 'therapeutic', thus making

the claim indefinite. This claim was examined on the merits whereby the M.citrifolia

retains volatile flavoring.

Please note that the Examiner's interpretation for claims that are indefinite are

not suggestions for rewriting the claims per se ,as the Examiner cannot conclude the

intended boundries of the claim limitations. Further, the interpretations are ideas which

were based on the Specification, but not taken verbatim from the Specification (i.e., if

Applicant wishes to amend the claims in a way which reflects the Examiner's

interpretations, Applicant is asked to review the claims for New Matter, for example, the

term 'non-aqueous' is not explicitly found in the Instant specification and to include it in

a claim may constitute a New Matter rejection under 35 USC 112 First paragraph).

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-11 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel (US 4,463,025) in view of Lumpur (1999) in light of Wadsworth et al.(US 6,254,913 B1)*.

Claims 9-11 and 14-16 are drawn to a method for freeze concentrating *Morinda citrifolia* comprising the steps of freezing the water in the *Morinda citrifolia* slurry, separating the water by sifting, freezing the non-water material by freezing at a lower temperature than was used to freeze the water, and collecting the non-water material. Claims are further drawn to wherein the *Morinda citrifolia* has pulp, wherein oil found in the *M.citrifolia* are not volatilized during concentrating, wherein the resulting concentrate retains the health benefits of the slurry, and wherein the resulting concentrate retains the *M.citrifolia* flavor and volatile flavoring.

Strobel (US 4,463,025) taught a method for freeze-concentrating fruit juice via freezing the indigenous water to form ice crystals, separating the ice crystals from the juice slurry, lowering the temperature of the freeze-concentrating apparatus below the

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temperature used to freeze the water, and collecting the concentrated juice thereby (col.17, lines 10-24). Strobel taught the preferred apparatus for ice crystal separation was the GRENCO Freeze Concentration unit (Col8, lines 47-52). Strobel commented that the "... filter at the exit of the tank retains all ice crystals of more than 100 microns in size'. Therefore, the filter acted as a 'sieve' for 'sifting'.

Strobel additionally indicated that when performing this process "...at least 65% of the volatile compounds originally present in the juice are... retained in this concentrated serum" (col.9, lines 27-29) and added that, although the preferred concentrate obtained via their freeze-concentration method was oranges, that the method was not limited thereto (col.6, line 67-col. 7, line 1).

Strobel did not explicitly teach wherein the method was beneficial for freezeconcentrating juice of Morinda citrifolia or wherein Morinda citrifolia contained pulp.

Lumpur (1999) disclosed that Morinda citrifolia juice had been distributed and sold around the world (page 1, Article).

One of ordinary skill in the art would have been motivated to have freezeconcentrated Morinda citrifolia juice in order to produce a juice product which required less packaging space, and which retained the volatile chemical constituents contained therein. The ordinary artisan would have had a reasonable expectation that the method Application/Control Number: 10/044,158 Page 11

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disclosed by Strobel would have worked equally well with *Morinda citrifolia*, or any fruit juice for that matter, since the method employed by Strobel did not allow the release of the majority of the volatile flavoring components of juice upon concentrating.

It was known in the art that M.citrifolia juice contained pulp as evidenced by Wadsworth et al.* (Abstract).

*This reference was cited to relay an intrinsic property of *M.citrifolia* juice and is not used in the rejection *per se*.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

June 19, 2003

Patricia Patten